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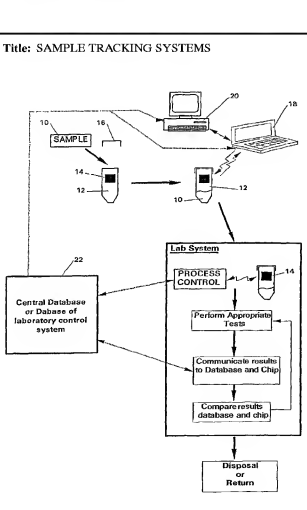
(54) Title: SAMPLE TRACKING SYSTEMS



(57) Abstract: A method of tracking and controlling the passage of samples through test procedures, which comprising the follwing steps. Introducing a sample (10) into a sample carrier (12) provided with a memory chip (14) that can store and provide tat that can be retrieved wirelessly. Programming sample specific data, such as the origin of the sample and the tests to be done, onto the chip (14). Introdicing the sample carrier and sample to testing appratus with chip reading means, and then elelctronically reading data on the chip (14). Performing appropriate processing and sorting on the sample. Loading at least partial details concerning the tests onto the memory chip (14) and finally using the sample specific data to return the test results and other data to a person who requested the test. The invention also includes sample carriers for use with such a method.

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Sample Tracking Systems

The present invention relates to a method of tracking and controlling the passage of a sample through a test procedure. It relates also to the capture, transfer, manipulation, and storage of data related to the sample. It further relates to a sample carrier acting as a data conveyance tool for use in such a system. It still further relates to methods of associating such data with a sample when loading into a carrier for use in such a system. The invention finds a particular application in the medical field, but it will be appreciated that its use is not limited thereto.

Testing often needs to be performed on a variety of samples provided from one or a number of locations. Such testing frequently requires the sample to be sent to a laboratory, which performs a test procedure or procedures on samples from a variety of origins. It is vital that the tests are correctly associated with the original source of the sample (for example a patient), that samples are correctly collected and transported to where they will be analysed and then subjected to the correct testing. It is further vital that results are correctly reconciled with other data associated with the original source of the sample and that the results are delivered to the correct users of the data. The only practical way to even try to achieve this, before now, has involved complex paper-based logging systems and the need for suitable documentation to accompany the sample when it is supplied to the test lab. Modern labs are becoming more and more automated, but even in such laboratories the necessity to enter this paper information into the control system has caused delays and increased the number of technicians required. In addition, the originator of a number of samples must repeatedly provide extensive information for each sample and this must be done manually. This operation is time consuming, and can lead to copying mistakes with potential medical or legal consequences. Together or independently these can dramatically reduce the efficiency of a testing system as well as the people who use it.

As mentioned above, the present invention will find particular application in the field of medical testing which is performed in clinical

laboratories, hospitals, medical practices and surgeries, and particular problems associated therewith will be discussed herein. However, it will be appreciated that the present invention is equally applicable to other sample testing situations, especially where the originator does not perform the tests.

In hospital environments the testing laboratories are often located at geographically separate facilities that serve a number of hospitals and/or doctors' surgeries. Medical staff, such as doctors, rely on the results of various testing procedures to make a diagnosis, to determine the appropriate treatment strategy, and to monitor a patient's condition. It is essential that a sample is correctly associated with a patient and the person making the testing request (hereinafter also referred to as a requestor) (e.g. a doctor). It is also essential that any locator information (such as the hospital or ward name), the correct request and collection time, and the identity of the sample collector (or sampler) is recorded and that the correct test is performed on that sample. The requestor may also need to indicate to the laboratory the speed that the results are required to effectively treat a patient.

Up to now, to effect testing, a sampler has to associate a sample that has been labelled with identifying key information, and supply a completed request form containing identical key information and other information required to process the sample. Both these items are then sent to the lab where a laboratory identifier system allocates an additional key to the sample and the form. This key is then used to maintain the association between the sample and the request form for when the sample is separated from the form to allow the sample to be analysed. The information on the request form is then manually entered into the laboratory system in association with the laboratory key. After the sample has been processed by the analyser, the laboratory key is required to reconcile the request and test result data. As a final step before authorising the result, the data on the original request form and the laboratory information system is re-checked for data entry errors. The results are then returned to the hospital ward or doctor's practice. There are significant delays associated with completion of the request, processing of the sample and delivery of the results. Once results are returned, the requestor will have to collect them from the place to which they were returned

(such as a hospital information system or medical record). Such a step is a time consuming inconvenience for busy medical staff.

Not only are such prior systems flawed from the viewpoint of the requestor, they are far less than totally efficient from the point of view of the testing facility. Modern labs use more and more automation to improve accuracy and efficiency. These automated labs use computers to control their operation, but the information supplied by the doctors is often in a written form so must be digitised at some stage, usually on arrival at the lab. This not only requires the lab to use more staff than is necessary, but the inputting of data can also lead to errors with the consequences discussed above.

It has now been appreciated that it is possible to overcome at least the majority of these problems and to provide systems of carrying-out testing that are a significant improvement on existing technology.

Therefore according to the present invention there is provided a method of tracking and controlling the passage of a sample through one or more test procedures, comprising the steps of:

- providing a sample carrier having an addressable non-volatile memory chip to which data may be stored and from which said data may be retrieved electronically using wireless transmission;
- introducing a sample to be tested into the sample carrier;
- programming sample specific data onto the chip, including the origin of the sample, details of a person requesting the results and/or a sampler taking the sample, and the test procedures to be carried out thereon;
- introducing the sample carrier and contained sample to testing apparatus including a chip reading means,
- electronically reading the sample specific data on the chip;
- performing appropriate processing, sorting, channelling and/or test procedures on the sample, in response to the sample specific data;
- loading at least partial details concerning the test results and the completion thereof onto the memory chip; and,
- using the sample specific data on the memory chip to supply details

concerning the test results and the passage of the sample through the test apparatus to the requestor.

The person requesting the test results is herein generally referred to as the requestor. The requestor may also be the sampler or may be a different person.

It may be advantageous for the sample specific data to include an identifier, which may be a code linked to the other data or may actually be derived from patient data recorded onto the chip pre-analytically (i.e. before it reaches the lab). Alternatively, or in addition, an identifier key may be imparted by the laboratory control system on arrival of the sample at the testing location. This laboratory identifier key may be used by the laboratory control system to trace and control the progress of the testing.

In most circumstances it is preferred that the steps of introducing the sample carrier to testing apparatus; reading the sample specific data; writing the laboratory key to the chip; performing appropriate processing, sorting, channelling and/or test procedures; loading details concerning the test results and the completion thereof onto the memory chip; and supplying details to the requestor; are controlled by a computerised laboratory control system.

The data carried on the memory chip is important. To meet the objectives of the present invention it is important that the information allows the results of the testing to be accurately recorded and returned to the requestor and associated correctly with the origin of the sample (e.g. a specific patient).

The possible data elements comprising the sample specific data could include:

- A carrier type identifier (e.g. identifies different types of test tube containing chemicals that enable certain tests. This is usually coded onto the sample memory chip on manufacture of the sample carrier)
- A sample type identifier (e.g. blood, urine etc.)
- Requestor data, (e.g. address, code number)
- Sampler/labeller identifying data (which could be that of the requestor)

- Return network or Internet Protocol (IP) address
- Patient data (e.g. name, age, sex, code number)
- Date/time tracking of events such as requesting, sampling, arrival in lab, testing
- Lab database identifiers
- Processing instructions to other machines
- Prioritisation data
- Test result data; and
- Tracking daughter samples made from the original.

The carrier class identifier mentioned above could be encoded during manufacturing of the carrier. The carrier class identifier could follow the ISO standard for test tube types so that all tubes have a consistent labelling system (Reference number ISO 6710:1995 (E)). For example, a full blood count carrier could have 1 as it's unique identifier and a glucose carrier could have 2 as the identifier. This would allow the person loading the sample into the carrier to automatically associate only the correct test requests with the specific carrier, easing the task of deciding which test request goes with a sample. There are over a thousand different clinical tests that can be performed on blood samples in twelve different carriers, which means it is difficult for people to remember.

A second important role of the carrier type identifier is in the laboratory where it will facilitate automated sorting of sample carriers rather than human action. For example the 3 variables required on the test tube memory chip for an intended sorting algorithm are: type of carrier, test type requested, and urgency of the request (prioritisation).

It is common for different laboratories to already have installed laboratory control systems that generate laboratory numbers that are unique for that system. That identifier may be loaded as a laboratory code onto the memory chip when the sample arrives in the laboratory. This allows labs to continue with the tracking code systems they already use, the present invention could simply interface with the existing lab control system with only minor modification thereof.

When loading the sample specific data on the memory chip, an identifier (or locator) unique to the requestor - such as a network address or Internet Protocol (IP) address - could be imparted to the memory chip. This locator may be the physical address of the device being used to program the chip, but would more likely be a "pointer" or "mailbox" address on the network or Internet that relays the message further according to a set of rules specified. In Internet Protocol terms this is known as a multicast IP address. This would allow results from tests performed on the specific sample to be returned to the mobile programming device that the originator used to conduct the work or perhaps to a personal mailbox on the network specified for the user that can flag up the availability of the result the next time the user logs on, thereby saving time and effort to look up the result.

The memory chip will also be programmed with information that could modify this reporting function depending on:

1. The urgency that results of tests performed on the sample are required; and,
2. The person that took the sample. If, for example, a laboratory phlebotomist took the sample, it would not be appropriate for the result to be returned to the phlebotomist ("sampler"), but should instead be returned to the responsible physician ("requestor").

One of the important features of the present invention is that all data required to process the sample may be provided on the chip, so making the system "network independent" - there should be no need for the laboratory control system to reference the requestor's database to link or retrieve data elements. However a link to such a database may be provided for verification or other purposes.

The initial process of getting the information from the memory chip into the testing apparatus or laboratory control system preferably involves reading the sample specific data from the chip, updating the laboratory database (part of a laboratory control system) with the data, associating a laboratory number with the sample specific data, and writing this laboratory number onto the memory chip. Most patient databases, whether GP or hospital based, usually allocate a database number to a patient. Knowing the origin of the sample

and a unique patient number within a database at the origin means a result can be accurately returned to the originator's database. Also there is increasingly within many countries a movement towards national unique patient identifiers, which could be used instead to identify the patient.

A further good reason to put all patient demographic or identifying data on the memory chip is that it allows the laboratory control system to make automatic comparisons to the normal values expected based on sex, age or other demographic data of the patients and therefore allow automatic authorisation of results. Currently only a few laboratories in Europe have bi-directional interfacing between the hospital information system and the laboratory control system to allow this feature to be implemented. Including the information on the chip obviates the need for such a link, which can be expensive to implement, whilst still providing the benefits.

On transfer to the laboratory, the sample carrier and contained sample could first be introduced to a registering apparatus. Such registering apparatus could be a memory chip reading/writing transponder linked to the laboratory control system. This could be operated by a human worker, or preferably by an automated carrier sorter with an embedded transponder.

An additional class of information that could be recorded onto the chip are instructions recorded in the lab during processing that inform "downstream" machines what should be done with the sample. A good example could include that an instruction be added to ensure that a single sample be split, or that a number of daughter samples be prepared, or that the contents be deposited in or on a different container such as a culture flask (virology), petri-dish (microbiology), DNA array chip (genomics), micro-titre plate (immunology/serology), or glass slide (cytology/histology). If a sample or part thereof is transferred to a new carrier the data stored on the memory chip of the original sample could be transferred to the new carrier, and both could be augmented with data that allows tracking of the transfer event.

In other instances it may simply be the identifying data, not the contents of the carrier vessel that should be transferred securely such as during preparation of blood products that have to be cross matched for blood

transfusion. In this way an unbroken chain of "positive identification" is obtained without human intervention.

Instructions could pertain to variables found during testing, such as volume of the blood sample, which may influence testing temperature control, incubation times or subdivision of the sample. Other uses envisaged are that blood that is obtained from a blood donor is tested for various pathogens such as hepatitis B or HIV and cross-matched. The results from those tests are imprinted on the chip to serve as a "certificate" of quality and origin (to counter uncontrolled sources of blood). In this example the carrier would comprise a blood bag provided with a memory chip

It is of course impossible to describe all the possible uses for the present invention and the testing regimes that could incorporate the basic concept of providing the sample carrier with an addressable memory. Clearly specific embodiments other than those described herein are apparent from the description.

The programming of sample specific data onto the chip may be performed by a requestor, or may be done by a sampler specifically tasked with taking the sample and despatching it to the test environment. For example, a doctor (the requestor) may place a request, possibly on a hospital network or on a patient tag carrying a tagging chip (see later) or simply by verbal or written instruction, and another person such a nurse or phlebotomist (the sampler) will take the samples some time later. In practice this happens in at least 60-70% of all medical sample taking. In these circumstances therefore details of both the "requestor" and the "sampler" could be included in the sample specific data. The sample specific data could also include the date/time of both requesting and sampling.

To impart the sample specific data onto the memory chip, users (such as requestors and samplers) will require some form of device capable of electronic wireless communication with the chip. This may be achieved using a personal data programmer (or personal digital assistant [PDA]). Personal digital assistants generally comprise a processor, display, data entry means such as a keyboard, and software applications running thereon. The personal data programmer may be capable of reading and programming the chip and

also able to communicate with a central database when present. Many commercially available products could be used if provided with the appropriate transceiver or transponder and control software.

The personal data programmer could interface with a local computer so as to transmit or store data. Alternatively, the personal data programmer could communicate directly with the laboratory control system or central database, for example using a mobile phone connection, wireless network or radio frequency communication.

Patient specific data such as date of birth, sex, name, address, and GP or hospital database numbers should go on the memory chip. As discussed before this removes the need for a central reference database, even though one may still be used. For example, in the UK a GP practice nurse have need to obtain a blood sample from a patient at home. In the process he/she could label the blood sample with patient specific information from a personal digital assistant which could contain a database of all patients registered with a GP, or instead the information could be input *de novo* into the personal digital assistant at the patient's home and the test tube be labelled with the information.

Preferably the testing apparatus is at least partially automated. For example, the transport mechanisms that carry the sample carrier, and/or the testing equipment themselves could be automated. Control of such systems would generally be integrated within the laboratory control system.

When the results are returned to a user it may be preferred that he is notified immediately if for example the requestor had prioritised the sample as URGENT or EMERGENCY. The results may be passively received by the requestor by means of their being sent by some form of electronic delivery system such as e-mail, SMS text messaging, or direct to the software on the personal data programmer. For this to occur the locator on the memory chip needs to include some physical address such as a network address or Internet Protocol (IP) address.

Alternatively, the data in the database could be actively obtained by the user accessing the database to view the information. This would remove the need for the sample specific data to include a complete return locator or

address, but might instead need it to have security or other access controlling information.

Communication between the database and the user, whether direct or through intermediary devices such as personal computers, could utilise any suitable communication network such as the Internet, Wide area network (WAN) or local area network (LAN).

To simplify the programming of sample specific data onto the chip it is preferred that the personal data programmer can interface with any local database that provides information on the origin of the sample. For example in a hospital, any computerised details held concerning the patient could be provided to the personal data programmer for loading onto the data chip. It is envisaged that the personal data programmer could interrogate the hospital's information systems, perhaps through wireless communication. Alternatively information on the patient could be provided on patient tags having addressable tagging chips similar to the memory chip included on the sample carrier.

In a further feature of the present invention, patients are provided with patient tags which would carry addressable tagging chips to store patient specific information. This information could be read in a similar way to the memory chip on the sample carrier by the personal data programmers prior to programming sample specific data onto the memory chip. Also a requestor could load details of samples to be taken on the tagging chip. A sampler could then read the tagging chip to discover what samples to take and what tests to order, as well as retrieving the patient data to program the sample specific data.

As the sample is tested in the laboratory or otherwise, details of the test results are loaded onto the memory chip and are also provided to the database or laboratory control system. To correlate the data and check for discrepancies, it is preferred that an additional step is performed wherein the data stored on the memory chip is compared to that on the laboratory control system (or central database if present). The data stored on the lab control system and that stored on the memory chip may then be compared after completion of each or all test procedures. If any discrepancies are found

between the test data on the memory chip and in the database the sample may be returned to the test apparatus to undergo appropriate re-testing.

A further reason to compare the data on the carrier chip and the laboratory control system would be to compensate for the fact that the analyser performing the test may not be connected to the network of the laboratory control system. This can frequently be the case where equipment from different suppliers is incompatible with the installed laboratory control system. Comparing the data allows the information on the laboratory control system to be updated with the result of the test procedure. A still further reason to load test results onto the chip is that the test results already performed on the sample are then readily available without reference to an external source, for example, if the sample is sent to another lab, or if the specimen is retrieved from storage for further testing.

According to the present invention there is also provided a sample carrier designed for use with a method as described above, which sample carrier comprises a base, side walls upwardly extending therefrom so as to define a lumen, the upper periphery of the side walls defining an opening through which a sample may be introduced into the lumen, and an addressable non-volatile memory chip attached to the base or side walls of the sample carrier and to which sample specific data may be stored and from which said data may be retrieved electronically using wireless transmission.

Preferably a resealable cap may be used temporarily to close the opening. The memory chip may be integrally formed with the material of the sample carrier, for example by embedding therein during manufacture. Alternatively the memory chip may be permanently or removably attached to the sample carrier after manufacture. The memory chip may preferably comprise a random access memory chip, connected to an aerial.

Sample carriers augmented with addressable memory chips according to the present invention would also allow the following functions to be developed as part of a fully automated system:

1. Robotic control mechanisms would be provided with radio frequency information from the microchip to assist accurate localisation of the sample carrier during manipulation; and,

2. Automated storage and retrieval systems for carriers that have completed testing. (Often clinicians request additional tests on samples that are already in the laboratory to save the necessity of taking another sample. Currently the laboratory technician has to retrieve the sample manually. Also different samples are kept in storage for variable lengths of time before being thrown away.)

The management of the storage system could be automated by having a robotic control system enhanced by a memory chip reader and instructed by the laboratory control system to locate the sample by detecting sample specific data. As an example of a "housekeeping" function, the system could detect all biochemistry samples in storage more than one week old and retrieve them for disposal.

According to the present invention, there is also provided a method of taking and labelling a sample from a patient, comprising the steps of:

- providing the patient with a identifying tag including an addressable non-volatile tagging chip to which patient data may be stored and from which said data may be retrieved electronically using wireless transmission;

- programming patient data onto the tagging chip;

- taking a test sample from the patient and loading the sample into a sample carrier having an addressable non-volatile memory chip to which data may be stored and from which said data may be retrieved electronically using wireless transmission; and

- electronically reading the patient data from the tagging chip and using said patient data to program sample specific data onto the memory chip.

By way of example only, various embodiments of the present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a flow chart of a simple embodiment of the present invention;

Figure 2 is a flow chart of a different embodiment of the present invention wherein the lab system is linked to a networked user database;

Figure 3 is a flow chart of a further embodiment of the present invention wherein the lab system is linked to a standalone user database;

Figure 4 is a flow chart of a yet further embodiment of the present invention wherein testing is carried out at the bedside;

Figures 5a, 5b and 5c show a sample being collected by a first sampling method;

Figures 6a, 6b and 6c show a sample being collected by a second sampling method; and,

Figures 7a and 7b show a sample being collected by a third sampling method.

Referring initially to Figure 1, a simplified flow diagram depicting a method according to the present invention is shown. In this method, a sample 10 is loaded into a sample carrier 12 incorporating an addressable memory chip 14. A lid 16 is placed on the open end of the sample carrier 12 to seal in the sample 10 and prevent contamination. A personal digital assistant (PDA) 18 is used by a person taking the sample (the "sampler") or a person requesting the test (the "requestor" - who may also be the sampler), to program sample specific data on to the memory chip 14 using wireless transmission. The personal digital assistant 18 may communicate with a personal computer 20 to transfer information.

The sample carrier 12 and contained sample 10 are then sent to a laboratory for appropriate testing. On arrival at the laboratory, the sample specific data held on the memory chip 14 is read and supplied to the laboratory's control system. A laboratory identifying number or code is imparted to the memory chip to aid the tracking of the sample by the laboratory control system. Appropriate testing procedures are then carried out on the sample either inside or outside the sample carrier. The results of these tests, as well as the progress of the sample, are communicated to a database 22. The database may form part of the laboratory control system or may be a separate central database. Indeed there need not be a database if the laboratory control system can supply the results directly back to the requestor. Not only are the results communicated back to the requestor, they are also loaded onto the memory chip 14.

The loading of test results on to the memory chip helps to ensure, along with the other information already stored thereon, that a sample carrier

is capable of imparting to someone reading the chip all information necessary for testing and evaluation without reliance upon a separate database or network. In addition, the results recorded on the memory chip can be compared to results recorded in the database and discrepancies can be used to trigger appropriate re-testing or other diagnostic functions. After testing is complete, the carrier and sample contained therein may be disposed of or returned to the point of origin. Alternatively, it may be stored in case re-testing is needed.

The results may be returned to a requestor (or a requestor's personal digital assistant 18) by several means as already described herein. In Figure 1, the results are provided to the database, which in turn supplies them to either the personal computer 20 or the personal digital assistant 18 through an electronic delivery system 24. This electronic delivery system would use locator information provided on the memory chip 14 to direct the results back to the requestor. The results could be returned directly to the requestor or possibly could be supplied to a mailbox to which only the requestor has access. By accessing the mail box the requestor could therefore retrieve the results.

As shown in Figure 2, the system could operate using a network linking the equipment of the requestor and/or sampler to the laboratory systems as well as a central database (which could include a control/overseeing function). In the method depicted in Figure 2, a sample 10 is loaded into a carrier 12 incorporating a memory chip 14 which is programmed by a personal digital assistant 18, or a personal computer 30, incorporating a smart reader (or transponder) 32. The personal digital assistant 18 and personal computer 30 are linked to a central database 34 either via a wireless or hard-wired LAN system.

On receipt of the sample at the laboratory, the sample initially undergoes sample registration using a transponder 36 linked to the laboratory control system. The laboratory control system then ensures suitable automated sample sorting and division and then controls the performance of appropriate tests on the sample. The results are then communicated to the central database and loaded onto the chip 14. Once received by the central

database the results are made available to the requestor by return to the personal digital assistant 18 or the personal computer 30.

On completion of the testing, the sample and sample carrier enter an automated storage and retrieval system. This storage and retrieval system permits the requestor to initiate further tests simply by issuing suitable instructions and sending these to the laboratory system *via* the central database. Upon receipt of suitable instructions the laboratory control system may re-initiate appropriate testing and subsequently communicate the new results back to the requestor. Such an automated storage and retrieval systems could also be used to dispose of samples in response to certain criteria such as age.

The method shown in Figure 3 is very similar to that described above in relation to Figure 2. However, it differs in that once the results are reported to the central database, the central database uses the locator information contained on the chip to return the results to a single non-networked machine. For example, the locator information could comprise the Internet protocol (IP) address of a requestor's computer 36 (e.g. a standalone PC in a doctor's surgery). In this way, the Internet could be utilised to return the results to a doctor who is not linked to a suitable private network. The main advantage of such a method is that, as long as all information is encoded on the sample carrier, before dispatch by the requestor, it is possible to return the results to the requestor without the need for a complicated network. The requestor or doctor requires only a personal computer (or other suitable means such a wireless application protocol [WAP] telephone, laptop computer, personal digital assistant) with a transponder to program the information on to the memory chip. The sample carrier and sample may then be forwarded by post or otherwise to a testing centre whereat the test results may be ascertained and provided to the central database. The central database could then, using the locator information, return the results to the requestor. This would probably occur by providing the results in a central mailbox system, which the doctor could access *via* the Internet using the same or different device to the one which was used to program the chip.

It is also envisaged, that certain near-patient analysis might be

performed as well as that done at a remote location. In such situations there is a danger that busy clinical staff would not take care to input all relevant and accurate patient and sample specific data into the control system of the analyser. The present invention offers a solution. In Figure 4 one particular method of local testing according to the present invention is shown. In this method of testing, a sample is loaded into a sample carrier with a program chip programmed in a similar way to that already described. Instead of despatch to a lab, the sample and carrier are introduced to a bedside analyser 40. This reads the chip 14 and registers the sample before running the test. The test results are stored on the memory chip 14 and are supplied to a requestor (or their personal digital assistant 18) directly - or through a central hospital database 42, possibly using a wireless LAN or networked personal computer 30 as previously described.

It is often important to ensure the accuracy of such bedside analysers. Therefore the samples may be subsequently forwarded to a full lab system where they are re-tested and a comparison is performed between results found in the lab against those on the memory chip 14. Alternatively, the data from such near-patient analysis may be forwarded to the laboratory for final checking and authorisation before publication. This can allow verification or recalibrate (possibly remotely) of the bedside tester 40 to maintain accuracy.

Development of the present invention has lead to the discovery of certain novel methods of loading samples into sample carriers. Figures 5a, 5b and 5c show a first method for secure loading of blood samples into a sample carrier for use in a method according to the present invention. Obviously this method could be adapted for other sampling, but sampling by venesection is exemplified because it is probably the most common sampling regime presently carried out in hospitals.

In this method and that described with reference to Figures 6 and 7, the patients are provided with personal tagging chips in addition to the usual hospital identity bracelet. These tagging chips are usually very similar to the memory chips associated with the sample carriers and they contain patient specific data such as name, age, sex, date of birth, even basic medical details such as allergies etc.

In Figure 5a the arm 50 of a patient is shown, and for convenience two veins 52 are high-lighted. A patient adhesive disk (plaster) 54, provided with a non-volatile tagging chip 56, is attached to the arm 50 by adhesive. A personal digital assistant 58 with a wireless transponder, and in contact by wireless connection with a central network, is used to store patient specific data on the patient adhesive disk 54.

During later events, a requestor (e.g. a doctor) can deposit requests for tests on the tagging chip 56 using the same or similar personal digital assistant 58. A copy of the request may be relayed to a phlebotomist by wireless network. The need for the test is therefore stored both on the patient adhesive disk, which a sampler can read independently, and on a task list supplied to the sampler directly (and verifiable by comparison to the tagging chip).

As shown in Figure 5b venesection (blood sampling) is commenced by inserting the needle 59 of a sampling device 60 such as a Vacutainer® into a vein 52 near the patient adhesive disk 54.

The sampling device is modified to include a transponder 61, capable of reading the patient adhesive disk 54. A sample carrier 62, incorporating a memory chip 64, and with a partial vacuum therein, is introduced in to the sampling device and blood is drawn therein (best shown in Figure 5C) by know techniques. The transponder then reads the patient specific data from the patient adhesive disk 54 and loads it on to the memory chip 64 of the sample carrier 62. The transponder also writes the remainder of the sample specific data to the memory chip so that sample and sample carrier are ready for transfer to the test environment. This simultaneous labelling of the carrier with data while introducing blood directly from the patient into the carrier offers the most secure means of associating patient identifying data with the carrier and sample.

A similar method is shown in Figures 6a - 6c. This method differs in that the patient specific data is held on a tagging chip incorporated in a bracelet 66. This prevents the simultaneous reading of the patient data and writing to the memory chip due to the incompatible positioning. Therefore the method is altered in that the patient specific data is read by the transponder

61 (Figure 6b) before taking of the sample (Figure 6c), and is stored on the personal digital assistant 58 before transfer to the memory chip whilst the sample carrier is contained in the sampling device.

In Figures 7a and 7b a third method for secure labelling of blood samples during venesections is shown. In this method patient specific data is stored on a bracelet 66 as already described. When a sample is to be taken, a conventional syringe 68 is used to draw blood from a vein 52. The patient specific data is read from the tagging chip 56 by a personal digital assistant 58, and stored thereon.

The blood sample obtained using the syringe 68 is, as shown in Figure 7b, deposited into a sample carrier 62 with a memory chip 64. The sample specific data (including the patient specific data obtained from the tagging chip 56) is then loaded on to the memory chip 64. The sample, and indeed any of the samples taken by the methods shown in Figure 5 or 6 are then sent to a testing environment and the results returned as already described.

Claims

1. A method of tracking and controlling the passage of a sample through one or more test procedures, comprising the steps of:

- providing a sample carrier having an addressable non-volatile memory chip to which data may be stored and from which said data may be retrieved electronically using wireless transmission;
- introducing a sample to be tested into the sample carrier;
- programming sample specific data onto the chip, including the origin of the sample, details of a person requesting the results and/or a sampler taking the sample, and the test procedures to be carried out thereon;
- introducing the sample carrier and contained sample to testing apparatus including a chip reading means,
- electronically reading the sample specific data on the chip;
- performing appropriate processing, sorting, channelling and/or test procedures on the sample, in response to the sample specific data;
- loading at least partial details concerning the test results and the completion thereof onto the memory chip; and,
- using the sample specific data on the memory chip to supply details concerning the test results and the passage of the sample through the test apparatus to the requestor.

2. A method as claimed in claim 1, wherein the steps of introducing the sample carrier to testing apparatus; reading the sample specific data; performing appropriate processing, sorting, channelling and/or test procedures; loading details concerning the test results and the completion thereof onto the memory chip; and supplying details to the requestor are controlled by a computerised laboratory control system.

3. A method as claimed in claim 1 or claim 2, wherein the sample specific data includes all information necessary to identify the origin of the sample, ensure correct testing, and to permit return of the results to the person making the test request.

4. A method as claimed in any of claims 1 to 3, wherein the sample specific data further includes an identifier code.

5. A method as claimed in claim 4, wherein the identifier code is derived from the sample specific data.

6. A method as claimed in claim 4, wherein the identifier code is a chip identifier which is linked to the sample specific data.

7. A method as claimed in any of the preceding claims, wherein a range of different sample carriers adapted for particular types of sample or tests are provided.

8. A method as claimed in claim 7 when dependant on claim 4, wherein the identifier code provides details of the class of sample or class of tests that a particular sample carrier is adapted for

9. A method as claimed in claim any of claims 2 to 8, wherein on introduction to the testing apparatus, and reading of the memory chip, a separate laboratory code is loaded onto the memory chip.

10. A method as claimed in claim 9, wherein the laboratory code is linked to the sample specific data and both are copied to the laboratory control system.

11. A method as claimed in any of claims 2 to 10, wherein the sample specific data is also transmitted to a computerised central database in communication with the testing apparatus or laboratory control system.

12. A method as claimed in any of the preceding claims, wherein the programming of sample specific data onto the chip is performed as the sample is taken.

13. A method as claimed in any of the preceding claims, wherein the sample specific data is programmed onto the chip using a personal data programmer.

14. A method as claimed in any of the preceding claims, wherein the test are returned to the requestor by means of a personal data programmer capable of receiving the results.

15. A method as claimed in claim 13 or claim 14, wherein the personal data programmer is connected to a local computer to transmit or receive data.

16. A method as claimed in any of claims 13 to 15, wherein the personal data programmer is a personal digital assistant.

17. A method as claimed in any of the preceding claims, wherein the results are sent to the requestor by an electronic delivery system.

18. A method as claimed in any of claims 1 to 16, wherein the results are stored until the requestor accesses them.

19. A method as claimed in claim 17 or claim 18, wherein the results are retrieved from the database through a communication network such as the Internet, WAN or LAN.

20. A method as claimed in claim 19, wherein the sampler specific data includes a unique electronic locator, such as an Internal protocol (IP) address, for return of the results to the requestor.

21. A method as claimed in any of claims 2 to 20, wherein the data stored on the memory chip is compared after completion of one or all test procedures, to information stored on the laboratory control system or central database.

22. A method as claimed in claim 21, wherein discrepancies between the test data on the memory chip and that stored in the central database or laboratory control system will cause the sample to undergo appropriate re-testing.

23. A method as claimed in any of the preceding claims, wherein the sample specific data incorporates details of sample prioritisation.

24. A method as claimed in any of the preceding claims, wherein the memory chip is connectable to the exterior of a sample carrier.

25. A method as claimed in any of claims 1 to 23 wherein the memory chip is integrally formed with the sample carrier.

26. A method as claimed in any of the preceding claims, wherein the memory chip is a random access memory chip, connected to an aerial.

27. A sample carrier for use with a method as claimed in any of the preceding claims, comprising a base, side walls upwardly extending therefrom so as to define a lumen, the upper periphery of the side walls defining an opening through which a sample may be introduced into the lumen, and an addressable non-volatile memory chip attached to the sample carrier and to which sample specific data may be stored and from which said data may be retrieved electronically using wireless transmission.

28. A sample carrier as claimed in claim 27, wherein a resealable cap is provided to removably close the opening.

29. A sample carrier as claimed in either of claims 27 or 28, wherein the memory chip is integrally formed with the material of the sample carrier.

30. A sample carrier as claimed in either of claims 27 or 28, wherein the memory chip is permanently attached to the sample carrier after manufacture.

31. A sample carrier as claimed in either of claims 27 or 28, wherein the memory chip is removably attached to the sample carrier after manufacture.

32. A method according to any of claims 1 to 26, wherein the sample is derived from a medical patient, and clinical testing is performed on the sample.

33. A method as claimed in claim 32 wherein the patient is provided with an addressable non-volatile tagging chip to which patient data may be stored and from which said data may be retrieved electronically using wireless transmission.

34. A method as claimed in claim 33, wherein information concerning the patient is read from the tagging chip and transferred to the memory chip in the sample carrier as part of the sample specific data.

35. A method as claimed in any of claims 33 or 34, wherein the details of the test or tests to be performed on the sample are loaded onto the tagging chip before sampling occurs.

36. A method as claimed in any of claims 33 to 35, wherein a requestor loads details of samples to be taken and tests to be performed on to the tagging chip, which samples are subsequently taken and loaded into a sample carrier by a sampler.

37. A method of taking and labelling a sample from a patient, comprising the steps of:

- providing the patient with a identifying tag including an addressable non-volatile tagging chip to which patient data may be stored and from which said data may be retrieved electronically using wireless transmission;

- programming patient data onto the tagging chip;

- taking a test sample from the patient and loading the sample into a sample carrier having an addressable non-volatile memory chip to which data

may be stored and from which said data may be retrieved electronically using wireless transmission; and

- electronically reading the patient data from the tagging chip and using said patient data to program sample specific data onto the memory chip.

Figure 1

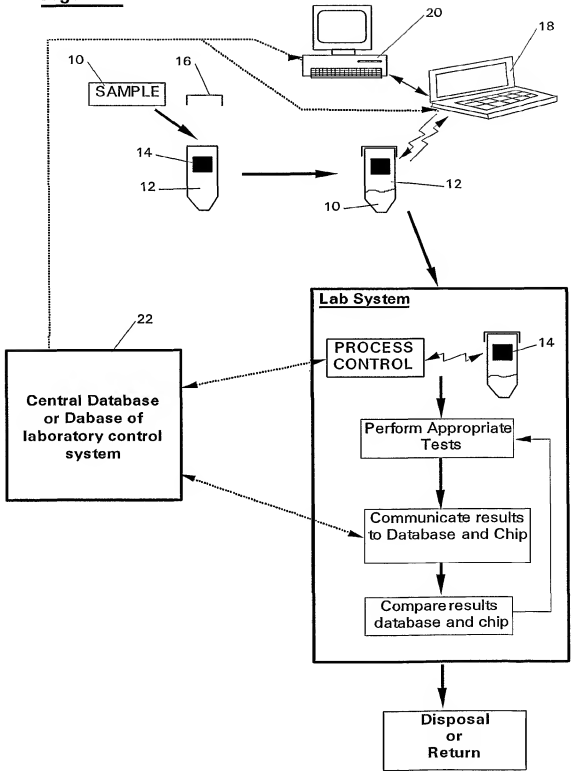
20
18
10
SAMPLE
16
14
12
12
10
Lab System
22
PROCESS CONTROL
14
Central Database or Dabase of laboratory control system
Perform Appropriate Tests
Communicate results to Database and Chip
Compare results database and chip
Disposal or Return

Figure 2

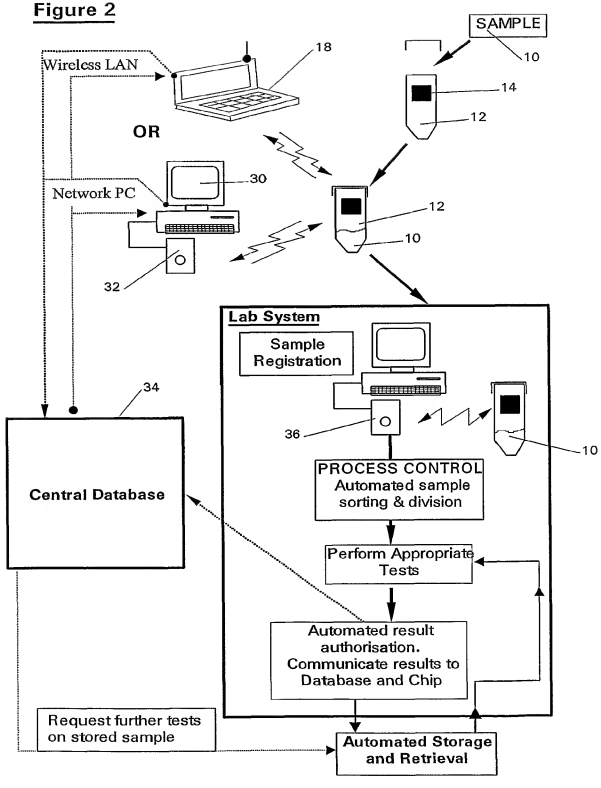
SAMPLE
10
Wireless LAN
18
14
12
OR
30
Network PC
12
10
32
Lab System
Sample Registration
34
36
10
Central Database
PROCESS CONTROL
Automated sample sorting & division
Perform Appropriate Tests
Automated result authorisation. Communicate results to Database and Chip
Request further tests on stored sample
Automated Storage and Retrieval

Figure 3

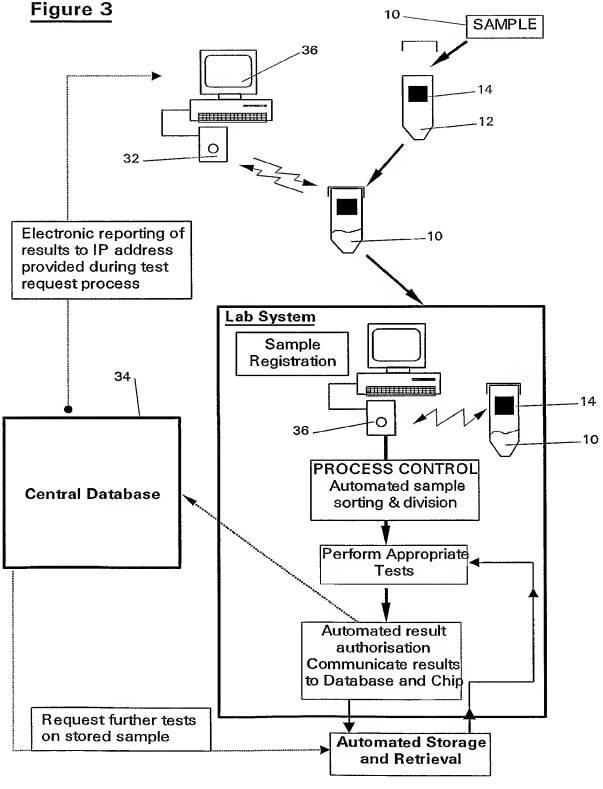
10
SAMPLE
36
14
12
32
10
Electronic reporting of results to IP address provided during test request process
Lab System
Sample Registration
34
14
36
10
Central Database
PROCESS CONTROL
Automated sample sorting & division
Perform Appropriate Tests
Automated result authorisation
Communicate results to Database and Chip
Request further tests on stored sample
Automated Storage and Retrieval

Figure 4

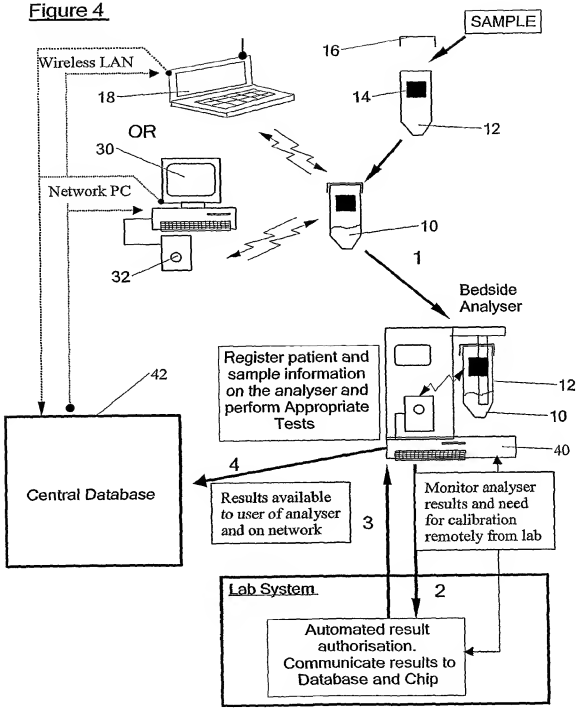
SAMPLE
16
Wireless LAN
18
14
12
OR
30
Network PC
10
1
32
Bedside Analyser
Register patient and sample information on the analyser and perform Appropriate Tests
42
12
10
40
4
Central Database
Results available to user of analyser and on network
3
Monitor analyser results and need for calibration remotely from lab
Lab System
2
Automated result authorisation. Communicate results to Database and Chip

Figure 5a

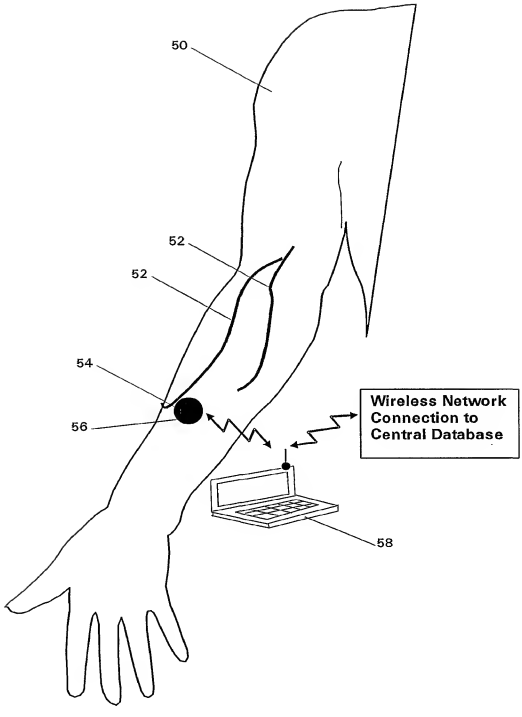
50
52
52
54
56
Wireless Network Connection to Central Database
58

Figure 5b

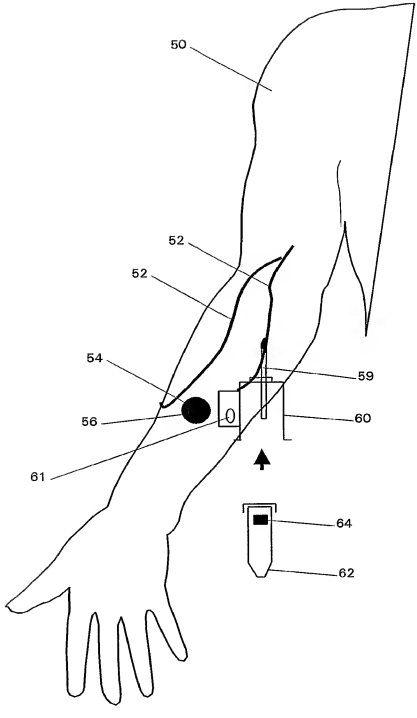

Figure 5c

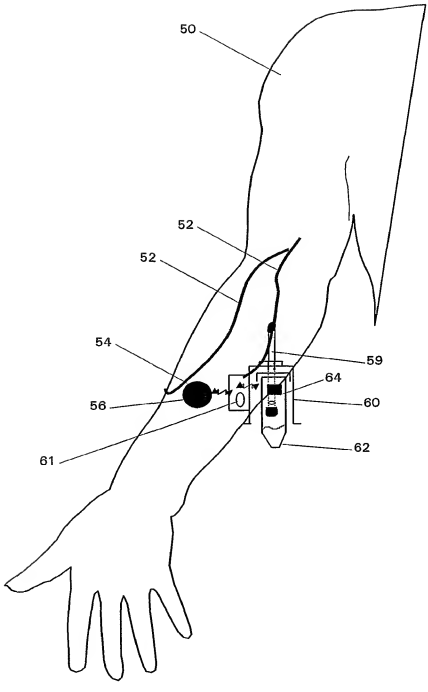

Figure 6a

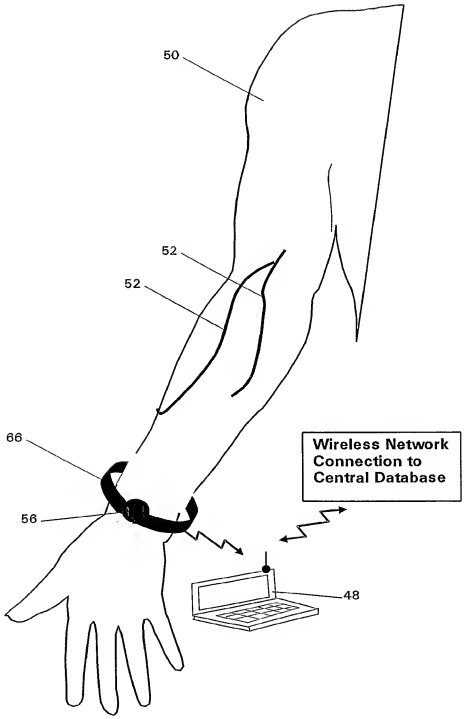
50
52
52
66
56
Wireless Network Connection to Central Database
48

Figure 6b

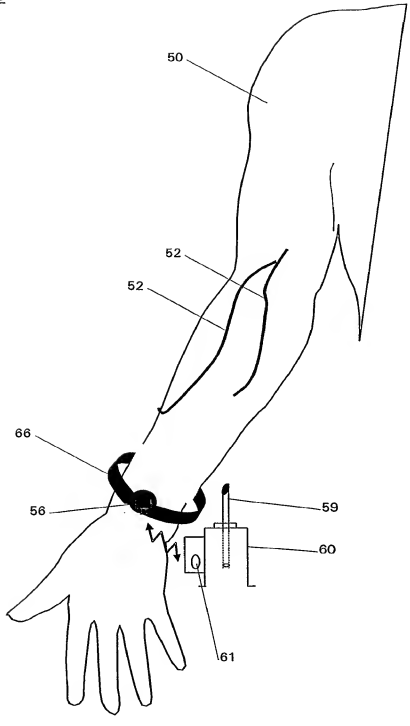

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Figure 6c

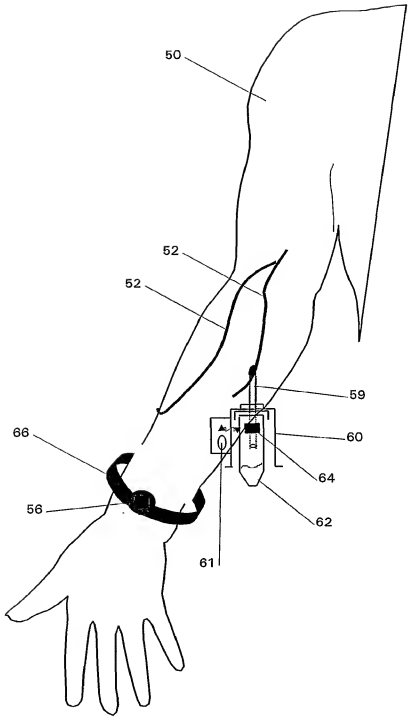
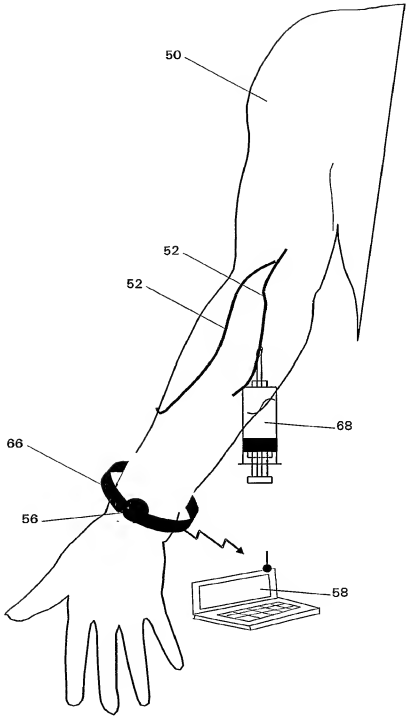


Figure 7a



5

Figure 7b